

F.No. 35022/10/2015-PI-III/PI-II(Pt)

Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

Shastri Bhawan, New Delhi
Dated, the 24th September, 2015

To

IDMA / IPA / OPPI / BDMA

Subject: Salient Features of the recommendations of the Katoch committee
Report on Active Pharmaceuticals Ingredients (APIs)

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Sir,

I am directed to refer on the above mentioned subject and to enclose herewith salient features of the recommendations of the Katoch committee Report on Active Pharmaceuticals Ingredients (APIs).

2. You are requested to provide your comments urgently and latest by 12th October, 2015 positively.

Yours faithfully

Encl: as above



(Raj Kumar)

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Copy to:

Director (NIC) with the request to upload the above on the above website of the Department today itself.

Salient Features of the recommendations of the Report of Katoch Committee on promotion of domestic manufacture of Active Pharmaceuticals Ingredients (APIs) / Bulk Drugs

In order to formulate a long term policy and strategy for promoting domestic manufacture of APIs/Bulk Drugs in the country, a High Level Committee headed by Dr. V.M. Katoch, the then Secretary, Department of Health Research was set up which submitted its Report in February, 2015.

The main recommendations of the Katoch Committee are as under: -

- (i) It needs to recognize that some of the issues of concern are generic to the entire Pharma Industry and not confined to the essential drugs alone. Therefore, measures will have to be taken for revival of the Pharma Industry as a whole including those involved in the manufacture of API intermediates. The key requirements for API industry include availability of land, basic infrastructure such as; water, electricity and Common state-of-art facilities such as Effluent Treatment Plants (ETPs), steam, testing facilities, etc. For economizing production, establishment of Large Manufacturing Zones (LMZs)/ Mega Parks for APIs with common facilities maintained by a separate Special Purpose Vehicles (SPV) will need to be explored. To begin with, such facilities will need to be provided at a concessional rate and preferably free of cost. This will help "in competing with the other countries and also generating large employment. Such mega parks need to be provided with

common facilities such common Effluent Treatment Plants (ETPs), Testing facilities, Captive Power Plants/ assured power supply by state systems, Common Utilities/ Services such as storage, testing laboratories, IPR management, designing, guest house/ accommodation, etc. These zones should be attached with power plants and solvent yards. These zones could be set up in National Manufacturing Investment Zones / Petroleum, Chemicals and Petrochemical Investment Regions (PCPIRs) in states that have the requisite facilities/systems in place. The State like Gujarat, Andhra Pradesh, Tamil Nadu and Odisha could be consulted and they could allocate the land and provide other facilities. Parks could be set up in the vicinity of mega complexes where chemicals meant for further stages in producing APIs could be produced. The bulk drug industry including those involved in the production of APIs is one of the major polluting industries. The cost of the pollution control is very high as it requires highly capital intensive technology to treat pollution. It is, therefore, necessary to have proper rules and regulations to have check on the pollution level and the quality of the output. But at the same time there is a need to come out with procedures of implementation which are efficient and effective which include aligning the provisions of the Acts and rules regarding pollution, quality control, custom and excise duty, export bodies (DGFT), coal allocating bodies, electricity authorities to have a cell in the mega complexes proposed for the bulk drugs.

- (ii) Six large API intermediate clusters in five to six states are

expected to transform the nation. Keeping in view the urgency it would be necessary to start with at least two fully financed clusters (one focused on fermentation and other on APIs) in the immediate future, this process may be driven by an Empowered Committee for taking decisions in a time bound manner. An average cluster will require about 1000 to 2000 hectares of land and will require about 750-1000 crore investment for common facilities/ services if all requisite schemes are developed and implemented in near future within 3-6 months. These parks could be allotted to large bulk, medium and small manufacturers on the basis of a formula to be specified in the guidelines which may be prepared by the Department of Pharmaceuticals. Because of similarities in technologies for chemical or fermentation technologies, separate parks for such manufacturers will be desirable. One such functional cluster can bring benefit of around one billion dollar/ Rs 60 billion per year. It is felt that three clusters may succeed in wiping out dependence in the area of APIs.

- (iii) A scheme for extending financial assistance to states to acquire land and also for setting up common facilities would be necessary. The States may also establish their own manufacturing zones for this purpose.
- (iv) Revival of public sector units for starting the manufacture of selected and very essential critical drugs (e.g. penicillins, paracetamol etc.) /vaccines or lease the plants/ assets possessed by these units is suggested as one of the options for consideration. Where feasible, it would be necessary to evolve

ways and means of utilizing the resources available in public sector units such as IDPL for setting up API industry. Infusion of capital (about 500 crores each) is recommended to these units to start manufacturing important APIs in the very near future.

- (v) In order to ensure single window clearance to manufacturers and provide common facilities and other support, the Department of Pharmaceuticals should have an institutional mechanism which could work in synergy with other important Departments such as Ministry of Environment and Forests, Ministry of Coal, Department of Financial Services, Department of Revenue and others have units co-located at the site.

Machines / Equipment:

The incentives to the manufacturers for setting up large plants and imports of technology that will reduce the cost of production need to be worked out. Allocation of adequate quantity of coal and electricity at concessional rates may also be considered. A scheme on the pattern of the modified special incentive package for IT hardware, etc. may be considered.

Fiscal and Financial Incentives

The following measures are recommended:

- (a) Immediate financial investment will be required from the Government for development of clusters which may be in the form of a professionally managed dedicated equity fund for the promotion of manufacture of APIs

- All central and state duties, taxes, levies etc in creating the entire community cluster infrastructure and individual unit infrastructure should be zero. If a unit promises more than 50% capacity utilized for NLEM products then at least these benefits should be given.
- (b) Soft loans to the Industry through interest subvention upto 7.5%, at least at par with interbank lending rates.
- (c) Capex loan to the manufacturers of APIs for high priority identified drugs, with a moratorium of 10 years for repayment. Alternatively debt instruments should be long term ie 3+5 years for APIs / intermediates and 3+7 yrs duration for fermentation.
- (d) Margin money for strategic projects should be cut down. Preferably to 15% equity and 85% debt.
- (e) Tax free status to cluster developers and cluster participants for 15 years
- (f) Measures to encourage foreign investment including faster clearances, funding for green field/brown field areas to be appropriately analyzed and support to be encouraged for the brown field technologies.
- (g) Income Tax rebates on up gradation of the existing R&D facilities should be doubled to 400% from existing 200% so as to encourage new development.
- (h) Income tax benefits for manufacturing companies for an initial period of 10 years for each product from the date of launch of the product.

- (i) Tax benefits in the form of proper indirect taxes.
- (j) A long term strategy keeping a goal of strengthening API sector by involving Ministry of Commerce as well as other regulatory authorities is required.
 - (i) Judicious and liberal use of measures like anti-dumping, safeguards/duties, reciprocation and application of rules of origin is suggested.
 - (ii) Based on risk analysis, a minimum of one or two inspections per month must be carried out for manufacturing facilities (by Indian regulators) located outside India.
 - (iii) Creation of advance testing lab infrastructure at all Indian ports / air ports in a time bound manner to subject imports to risk-based testing.
- (k) Incentives such as reduction on service tax on the clinical trials for drugs developed in India.
- (l) Assured percentage of procurement from domestic bulk drug manufacturers from mega parks in conformity with WTO norms.

RESEARCH AND DEVELOPMENT

Committee recognizes that investment in R&D is essential to ensure competitive edge. Measures recommended are:

- (i) Stronger industry-academia interaction by facilitating the to-fro movement of scientists between industry and academic institutions.

(ii) Institutional mechanism for Ministry of Human Resources, and various Science departments/agencies like DST, DBT, CSIR, ICMR etc to work together/ in synergy on R&D relevant for best procedures of production.

(iii) Innovation should be measurable and awards to the scientists/industry who contribute to the development of improved processes relevant to bulk drug industry. Technology development financing - to be repaid.

(iv) Import Duty Exemption on import of Capital goods In respect of research and development (R&D) and Manufacturing of Vaccines / APIs.

(v) Other tax benefits/financial incentives/support from Govt for R&D for development of improved strains; alternate raw materials, and improved/competitive technologies.

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